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RECORD OF ORAL HEARING

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS

AND INTERFERENCES

Ex Parte AVRAHAM J. DOMB and
JOSEPH S. WOLNERMAN

Appeal 2008-003664
Application 10/083,413
Technology Center 1600

Oral Hearing Held: May 11, 2010

Before CAROL A. SPIEGEL, DEMETRA J. MILLS, and
STEPHEN G. WALSH, *Administrative Patent Judges.*

APPEARANCES:

ON BEHALF OF THE APPELLANT:

MICHAEL TERAPANE, ESQUIRE
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THE USHER: Good morning. Calendar No. 41, Appeal No. 2008-3664, Mr. Terapane.

JUDGE SPIEGEL: Good morning. I'd like to welcome you to the Board of Patent Appeals and Interferences. We are here for oral arguments on Appeal No. 2008-003664, in the matter of *ex parte* Domb, D-o-m-b, Application No. 10/083,413. If counsel will kindly introduce himself and his guest, you will have 20 minutes and may begin whenever you like.

MR. TERAPANE: Thank you very much.

Good morning, Your Honors. My name is Michael Terapane. I represent the assignee of the application in question, which is Efrat Biopolymers, Limited. I am joined today by Dr. Avi Domb, who is one of the named inventors on the Application in question.

To start, I'm going to address the 102 rejections that have been raised by the Examiner. Dr. Domb is then going to give some brief comments on some technical issues with respect to the polymers in question, and then I'll follow up with some final comments on the 103 rejection that was asserted by the Examiner.

Okay. So the Examiner made two rejections under 102(b). The first was over U.S. Patent No. 4,772,470, and I apologize if my pronunciation is incorrect, I believe it's Inoue, and I'll refer to it as Inoue.

Claim 1, pending Claim 1, has a limitation that the concentration of the bioadhesive material or materials is from 40 to 99 percent by weight of the composition. This limitation is not disclosed or suggested anywhere in the Inoue reference.

Now, the Examiner has cited a couple passages where she believes there is -- this limitation is disclosed. And, for example, she cites Column 3,

line 24, to Column 4, line 31, and Column 5, line 66, to Column 6, line 21. The passages she cites actually disclose percent dissolution of the polycarboxylic acid polymer when it's formed into this compatible mixture of compatible combination that Inoue describes. So it's not a disclosure of the concentration or the amount of the polymer that's in the entire composition, or the whole composition, which is the limitation that we have.

JUDGE SPIEGEL: Counsel?

MR. TERAPANE: Yes?

JUDGE SPIEGEL: If I might direct your attention to Column 9, the paragraph beginning around line 54?

MR. TERAPANE: Okay. Column 9, you said?

JUDGE SPIEGEL: Yes, sir.

MR. TERAPANE: Okay.

JUDGE SPIEGEL: If we have a disclosure of the amount of topical drug to be applied, along with a disclosure that excipients are present in minor amounts, why would not a disclosure of a topical drug, ranging from 0.0001 to 35 percent by weight in a subtractive mode give us an amount of bioadhesive within the claimed range?

MR. TERAPANE: Okay. So there's two reasons. One is that the compatible mixture of polymers is a polycarboxylic acid, which is adhesive, and polyvinyl acetate, which is not. The polyvinyl acetate polymer, its function is to affect insolubilization of the polyvinyl acetate. So the actual material that's bioadhesive here is the minor component of this compatibility or of this mixture of compatible polymers. If you also go on and read Inoue, this --

JUDGE SPIEGEL: I'm sorry. Explain that to me one more time.

MR. TERAPANE: Sure. So the -- what Inoue discloses is a compatible mixture of polymers, where one of the polymers is polycarboxylic acid, which would be the adhesive component, and then there is a second polymer, which is polyvinyl acetate, and that polymer's function is to interact with polycarboxylic, to make it insoluble. It overcomes or addresses some at least deficiencies that Inoue believes exist with respect to using just polycarboxylic alone. So --

JUDGE SPIEGEL: So you would have us parse the bioadhesive of Inoue into two separate adhesive components?

MR. TERAPANE: Well, actually, not into two separate adhesive components, into the one component that is adhesive, which is the polycarboxylic acid. The polyvinyl acetate material is not bioadhesive.

JUDGE SPIEGEL: I'm sorry. Could you point to me where in your Brief that argument was made?

MR. TERAPANE: I think we addressed the -- we did address the weight percent, total, and talked about it in the context of the fact that Inoue talks about compositions where that adhesive film is then adhered onto a backing or a support film, so now you have the additional weight of that material.

JUDGE SPIEGEL: No, no, that wasn't my question. My question was where in your Brief did you raise the argument that we should look at the bioadhesive in Inoue without the film support layer, in terms of two separate components?

MR. TERAPANE: I don't believe we addressed that point explicitly. I think --

JUDGE SPIEGEL: And you're making it now for the first time?

MR. TERAPANE: Well, no. I think -- I mean we did address the fact that our limitation goes to the bioadhesive materials of the polymer and that Inoue doesn't disclose a bioadhesive material that exists in that percentage. So while we didn't explicitly parse out the polycarboxylic acid component of Inoue and the polyvinyl acetate component, we did, I think, implicitly make that argument when we talked about our limitation, which is to the bioadhesive material or materials in our composition and the fact that Inoue does not disclose that percentage, that weight percent, of a bioadhesive material.

JUDGE SPIEGEL: And in your own specification when you discuss preferred materials on page 12, and the second paragraph, where you talked about a particularly preferred carrier as a bioadhesive, composed of mixtures of slightly cross-linked polyacrylic acid, carboxyl-methyl-cellulose and hydroxypropyl-methyl-cellulose, aren't we getting into the same sort of parsing, based on what your specification is defining as a bioadhesive, more particularly, going to the number of examples you have, which are just a Carbopol in mixture with an HPMC?

MR. TERAPANE: Right, but the HPMC polymer has adhesive properties, as well. It's got either poly-hydroxyl, or multiple hydroxyl groups, or multiple carboxylic acid groups, depending on which -- whether it's -- if it's hydroxypropyl-methyl. So this would be multiple hydroxyl groups if it's carboxyl; it would be multiple carboxylic acid groups.

So, for us, that combination is -- those are bioadhesive materials together. And so, right, if you look at the working examples, we have both Carbopol and HPMC, both of which are bioadhesive or have bioadhesive

properties and are well within that 40 to 99 -- or, excuse me -- 95 percent range that we have in the claim.

JUDGE WALSH: Just is the carrier in the claim, in Claim 1, Part B, pharmaceutically acceptable solid bioadhesive carrier, is that present in the amount from 40 to 99 percent?

MR. TERAPANE: I'm sorry. You're reading from Element B?

JUDGE WALSH: Yes.

MR. TERAPANE: Right. So, in other words, when we use the phrase bioadhesive carrier, what we mean there is all of the bioadhesive materials that are in this composition, whether it's a single polymer or multiple polymers.

JUDGE WALSH: And that would be 40 to 99 percent?

MR. TERAPANE: Correct.

JUDGE WALSH: Okay.

JUDGE SPIEGEL: And what you're saying about Inoue is his bioadhesive polymer is limited to the polycarboxylic acid portion of it?

MR. TERAPANE: Correct. And so if you look at the examples in Inoue, for instance, for those ones where there's a support film, we don't know what the weight of that support film is, so ultimately we don't know what the absolute concentration or absolute amount of the adhesive component is in that composition.

JUDGE WALSH: If you're --

JUDGE SPIEGEL: But the support film isn't a bioadhesive carrier, as you cited in your claim. That's simply a -- would be encompassed by the comprising element.

MR. TERAPANE: Right, but our weight percent is by weight of our entire composition, so everything that would be in the composition, including the active agent and any other excipients that would be there.

And so, if you look at the examples in Inoue, once again, with those ones that have a support film, we don't -- that's part of the entire composition. We don't know what the weight of that is, so we don't know ultimately what the concentration of the bioadhesive polymer is.

For the one example, I believe it's in Table 6, where there's not a support film used, the bioadhesive component is less than 40 percent. I think it's 20 parts total, and it's 6 parts of the poly-acid, 14 parts of polyvinyl acetate. So where there is a little bit of disclosure about what things might look like without a support film, you're looking at, at best, maybe 40 percent, and once you start throwing in active agents and other excipients, your percentage is going to drop. So there's no disclosure of the 40 to 90 -- excuse me -- yeah, 40 to 99 percent of the bioadhesive material or materials in Inoue.

The second point I want to make, the second claim element or claims that we want to discuss are Claims 2 and 3, which to go the thickness of the composition. The Examiner has cited a couple passages, as well. If you read Inoue, it discloses making very, very thin films. Matter of fact, the total thickness of the film, that is adhesive layer plus support layer, is 30 to 150 micrometers, which is .03 to .15 millimeters. And Inoue actually says anything thicker than that we think gives either a foreign feeling in the mouth or adversely affects the soft properties of the film. In Claims 2 and 3, we have thicknesses of .4 to 2.3, and then 1 to 2 millimeters, which are

obviously much thicker than Inoue. So there's no disclosure of that thickness range in Inoue either.

JUDGE SPIEGEL: But now, in that argument you would have us read Inoue to exclude the thickness contributed by the film support layer?

MR. TERAPANE: No, you could look at it either way.

JUDGE SPIEGEL: I could look at it either way?

MR. TERAPANE: Right. In other words, the total -- if you look at Inoue, it says the total thickness of the composite film, which is the adhesive film, plus the support film, is 30 to 150 micrometers, which is a total thickness of .03 to .15 millimeters. I believe it says for the support film itself they typically give it -- they don't typically -- they give a range of 10 to 100 micrometers, which means you're talking about a film thickness for the adhesive film of about 30 to 50 micrometers. But the total thickness is -- so in that case, we're looking at, right, both films there.

JUDGE SPIEGEL: Okay. While we're on dimensions, if you would be kind enough to turn to your Claim 38, please?

MR. TERAPANE: Sure. Yes?

JUDGE SPIEGEL: We have a disclosure in Inoue of a circular disc with a diameter of 10 millimeters.

MR. TERAPANE: Okay.

JUDGE SPIEGEL: As I remember geometry, vaguely, in a distant memory, that would come out to a surface area of 0.314 centimeters square, which would read upon or about 0.4.

MR. TERAPANE: Okay. I think with respect to Claim 38, we would once again point out that it depends from Claim 1 and we have this limitation with respect to the composition, the amount of the bioadhesive

material or materials which is not disclosed in Inoue, and therefore, this claim would be patentable over Inoue, as well.

JUDGE SPIEGEL: So the separate argument with regard to Claim 38 would be withdrawn?

MR. TERAPANE: Well, you know, it's a little -- it may be a little bit difficult because we're talking about such small thicknesses of the films, and so surface area not only --

JUDGE SPIEGEL: No, this is the surface area. We're not dealing with volume. It's a two-dimensional calculation, not three.

MR. TERAPANE: I mean let's -- I guess if you gave about -- sort of the meaning that's generally assigned to it, which is usually about plus or minus 10 percent, that would give us .36, which is still outside the surface area range.

JUDGE SPIEGEL: Again, I'm sorry, but unless you can point me to that definition in your specification --

MR. TERAPANE: Okay. I mean I think I would argue that from about is -- .4 would exclude something as small as .315, which I believe is the number you gave.

JUDGE SPIEGEL: Because it's quite frequently that you go within the same decimal point, so we could be, you know, .4 give or take --

MR. TERAPANE: Okay. I mean I would argue that it excludes it, but then I would also make the argument that it depends from Claim 1 and there are differences there, as well.

JUDGE SPIEGEL: Okay.

MR. TERAPANE: And then the last point, claims we wanted to discuss, are Claims 22 and 26, which goes to -- 22 has a limitation that the

polycarboxylic is cross-linked, and then Claim 26 is specific, or provides a list of polymers that are cross-linked to that polycarboxylic acid. There is no disclosure in any way, or suggestion at all, of using a cross-linked polycarboxylic acid. It does talk about homo-polymers and copolymers.

The Examiner appeared to make an argument that there was maybe -- I'm not sure if she was suggesting an inherent disclosure, but that's how I read it -- an inherent disclosure of a cross-linked polymer by virtue of the fact that Inoue describes you can add a basic material to neutralize the carboxylic acid groups that are on the polymer. And the reason for doing that is to reduce irritation at the site of administration of the film.

So a couple points. First, is some of the materials that can be used are -- you know, your traditional base is not a metal salt; it's like a metal-based base, as well as monovalent ions. That you -- those would not cross-link because they're not able to.

If you look at -- she provided a secondary reference, which was a book chapter to -- or an excerpt from Odian, in which she talks -- she cites a passage talking about ionomers and cross-linking of ethylene copolymers that contain a very, very small amount, less than 10 percent, of an acrylic acid or methyl-acrylic acid monomer. And this passage goes on to say that these polymers act like reversible cross-linked polymers, not that they are cross-linked but that they act like it. This is not a disclosure of a cross-linked polymer, and I think more to the point, cross-linked --

JUDGE SPIEGEL: But it says, further on in that paragraph "subsequent to processing, the product becomes cross-linked on cooling."

MR. TERAPANE: Right, but that's a polymer -- that polymer exists by itself. In Inoue, you have a polycarboxylic acid polymer that is in a

compatible combination with a polyvinyl acetate, which interacts with that polymer. So, number one, there's no disclosure or suggestion that you would actually get the cross-inking that she's talking about because you have this other interaction going on between the polycarboxylic acid and the polyvinyl acetate.

The second point I would make is that cross-linking, as it's used in polymer chemistry, means covalent bonds between the polymer chains, not ionic interactions like we have here.

JUDGE SPIEGEL: And just what reaction do you think is going on, other than a copolymerization between those two components in Inoue?

MR. TERAPANE: That, I don't know. There's no disclosure or suggestion in Inoue of what type of discussion -- what type of interaction is going on between the polymers. All we know is that Inoue says --

JUDGE SPIEGEL: And yet, you're postulating that this -- the reaction with a neutralization-based salt is not going to occur.

MR. TERAPANE: Well, once again, the --

JUDGE SPIEGEL: And, you know, it's --

MR. TERAPANE: -- the interaction --

JUDGE SPIEGEL: You can't have it both ways. Which way is it?

MR. TERAPANE: Well, I don't think I'm asking for it both ways. I mean the passage that's cited by the Examiner was to a very specific polymer that exists by itself. We're talking about a combination of polymers that clearly have some interaction between each other, and there's certainly no disclosure or suggestion of cross-linking, but I think more to the point, the second point I made, which is that cross-linking, as used in polymer chemistry means covalent bonds. There is no covalent bond formation in the

ionosphere for -- yeah, the ionomer, excuse me, passage that the Examiner cited from this reference. So you can distinguish it on that point if there's some, you know, ambiguity as to what type of interaction may be going on.

Okay. The second rejection the Examiner made under 102 was over U.S. Patent Number --

JUDGE SPIEGEL: Yes, it's to Nagai, so just in the interest of time here, would you explain to me why, in Column 6, line 7, where Nagai refers to a cardiac tonic, we shouldn't interpret that as an extract?

MR. TERAPANE: Which line? I'm sorry. What line number were you at?

JUDGE SPIEGEL: I believe it's 7.

MR. TERAPANE: Okay. Cardiac tonics, such as digitalis --

JUDGE SPIEGEL: So he's not referring to digitalis per se but, rather, to a tonic. Why would that not broadly the read on an extract?

MR. TERAPANE: Well, I think the question -- I don't know that it reads on an herbal extract, which is what our claim requires. I mean it doesn't say what that's an extract of. I mean it just says -- I mean it says a tonic. I don't know what that term means. I'm not familiar with that term in the art, and it's not defined, so I don't know what's meant by that term, specifically

But there's not disclosure in here of an herbal active agent, as we define it, which is an herbal extract --

JUDGE SPIEGEL: But there is no disclosure to preclude a cardiac tonic from being an herbal extract either. Digitalis is well known to come from a plant.

MR. TERAPANE: Sure, and --

JUDGE SPIEGEL: You know, the term cardiac tonic probably goes back to the 1800s.

MR. TERAPANE: Right. I mean I think -- you know, the argument that we have made and that we would make here again today is that while certainly there are drugs in this list which initially or originally were isolated from a plant are now made synthetically. What we're talking about is an extract --

JUDGE SPIEGEL: But I'm asking you specifically about the phrase cardiac tonic.

MR. TERAPANE: Well, that term is not explicitly defined. I'm not sure what is meant by that term. I know that for us an herbal extract is a complex mixture of compounds. I don't -- this says cardiac tonic, such as, and it seems to refer to a single compound, so to me that would appear to be a single compound, not a complex mixture of compounds, like you would expect to find.

JUDGE SPIEGEL: Yet, when you read the other examples in that paragraph, when it refers to a single agent, it refers to it by name, not as a tonic.

MR. TERAPANE: That's correct. I mean --

JUDGE SPIEGEL: But there does seem to be some attempt to separate a tonic from a single agent.

MR. TERAPANE: Well, but a tonic could also simply be a solution of a single entity or a single drug, you know, in some sort of solution or suspension. Once again, I'm not familiar with that term, specifically. I don't know -- it's not defined here, and I don't know what a standard definition of that term would be, but it seems to me that it's referring to a single agent,

and not a complex mixture of agents, like you would get with an herbal extract.

JUDGE SPIEGEL: Okay. Would you like to touch on the 103, briefly?

MR. TERAPANE: Okay. Can I make one very, just quick --

JUDGE SPIEGEL: Sure.

MR. TERAPANE: I know we're running short on time. The only other thing I want to add about Nagai also, is we have the same arguments here with respect to the cross-linked polymer. In Claims 22 and 26, once again, there's a polyacrylic acid component here. It's described as being a homo-polymer or a copolymer. There is not disclosure or suggestion in Nagai of a cross-linked polymer as in Claim --

JUDGE SPIEGEL: Again, if you'll excuse me?

MR. TERAPANE: Sure.

JUDGE SPIEGEL: Nagai specifically references using Carbopol 934 as a polymer, and that is listed in your specification as the preferred polymer.

MR. TERAPANE: Could you point to where in Nagai that's --

JUDGE SPIEGEL: Well, for example, Example 3, at Column 13, around line 51.

MR. TERAPANE: Column 13. I'm going to have Dr. Domb address that issue, as well as some other technical issues with respect to the polymer, if that's okay?

JUDGE SPIEGEL: Okay. Did you want to do the 103 --

MR. TERAPANE: Yeah, I mean --

JUDGE SPIEGEL: -- or switch over? What's your pleasure?

MR. TERAPANE: I'd actually like -- I'm going to let him actually address your point, as well as some others, and then if we have a quick -- I can address the 103 very quickly, but --

JUDGE SPIEGEL: Works for me.

MR. TERAPANE: Okay.

JUDGE SPIEGEL: I'd like to welcome you to the Board, sir.

DR. DOMB: Thank you very much. Okay. My name is Avi Domb, and I will address the issue of cross-linking polyacrylic acid cross-linked material. This is necessary for a true adhesion to the mucosal tissue. Mucosal tissue is a polysaccharide that is catatonic in nature. So you need the polymer in order to form a good adhesion. You need the anionic polymer; it would penetrate into the catatonic poly-saccharide and form an interruption.

Now, if it is a linear material, then the linear material may penetrate and go in and stay there, and will not stay in the border between the disc and the surface of the mucosal. So, but if you have the cross-linked material, then only the chains that are free, they would penetrate in and form this adhesion. And this adhesion will intensify this time as the chains, they soften and penetrate inside. If you take a linear polymer, the polymer may penetrate in and stay there. This is also a toxic issue of what this polymer will do later on in this site.

In our case, when we have this adhesion, this adhesion intensifies with time. So you don't have the risk of something that will pull out a solid material and then may cause a choking of the patient. While the others, in both Nagai and Inoue, the material is non-erodible. Okay, to stay there, then you have to take it off. And the adhesion is not as intensive, or not --

intensifies with time, so it may -- later on, it -- you don't have control on the pull out of this material.

Now, with regard to Nagai, the Carbopol -- I don't know if the Carbopol at that time in '88, what was the composition of it. And now, but Nagai mentioned the chemistry of what is the polyacrylic acid. If you see that it is either homo-polymer or copolymer with certain monomers, none of them is tetravalent material, okay. It is -- in order to get the cross-linking, you have to have divinyl monomer, such as divinylbenezene or ethylene glycol -- those are not listed in the list of Carbopolization that Nagai is suggesting. So it can be called Carbopol 934. At that time, in '88, I'm not sure if this is the one that is used in the 2000 year, and I don't know if he made this analysis.

Another issue of cross-linking is the swelling. If you have a cross-linked material, it has a restriction of swelling. So the disc that you put is restricted with inflating. Nagai is explaining and showing that even after 10 hours, 70 hours, this disc is expanding by 70 percent. This is -- and for a device, for a perspective, you want something that will stay in the place and will not inflate and cause bulky material into your mouth.

With regard to the herbal stuff that was discussed here, I should mentioned that herbal components is not just a single material. It is a complex material that can contain hundreds of components that only these active agents in this composition are active. If you use something as -- or you lose some of the materials, even a minor amount, then you get a different activity.

Now, when you heat a material, such a material, you may lose some of them, like in the Inoue process, where he is using 80 -- he was using

higher temperatures. You may also get new materials that are combined by several materials in this composition.

I would like to give you an example from our product. We have a product -- the only one in the market, despite the fact that the many companies tried to mimic and do something similar. This one, we use citron oil as an active agent. Now, citron oil contains 90 percent lemon oil and 8 percent of about 50 different terpenes . This one works very well. When we switched to lemon oil, which is 70 percent lemon and 30 percent of different terpenes, but not the same terpenes that are in the other one, which was much less, okay.

So this is very important to keep the composition, a certain composition of an active agent as we're concerned. So it's not just selecting as -- excluding a material. This is a constant by itself. I'm saying from a commercial view point, to make a device, such a device, and make it commercial and pass the FDA, if you have a drug, then you have a process.

With the herbal materials, you can get the same effect, even a better effect, without all the need for the safety issues that you are required with a steroid, for example, that is used for treating of the same disease or same type of lesions in the mouth. Thank you.

JUDGE SPIEGEL: Just, sir, excuse me. So, if I understand you correctly, then you're saying your claimed invention would preclude a support layer, as disclosed in the reference, such as an aluminum coil?

MR. TERAPANE: No, that's not quite accurate. If you look at the working examples we have --

JUDGE SPIEGEL: No, I'm talking --

MR. TERAPANE: -- usually a multilayer tablet, which is one layer which has a bioadhesive polymer, as well as the active, and then we can also have a backing layer that's also compressed onto there that also has bioadhesive material and other excipients. So when we say whole composition, we mean, you know, the whole composition, whether it's a single-layer tablet or a multilayer tablet.

JUDGE SPIEGEL: But one of those layers could not be, for example, a thin foil of aluminum?

MR. TERAPANE: It likely would not be, because what we're looking at is a compressed tablet. It's the preferred embodiment. So most likely what you'd be talking about is layers of material that are compressed together to form a tablet, not a foil.

DR. DOMB: And it should be fully erodible.

MR. TERAPANE: Which -- right, which would certainly --

DR. DOMB: Fully erodible. Okay, we put it once and that's it. You don't need to come and take it off. This is --

JUDGE SPIEGEL: Yeah, but the problem is the claim doesn't say that.

DR. DOMB: Fully erodible. This is --

JUDGE SPIEGEL: Thank you very much, sir.

MR. TERAPANE: Okay. I know we're very short on time, so I'll just address the 103 very quickly. I redirect the arguments we made with respect to Inoue under 102. With respect to the amount of the bioadhesive material, the dimensions, as well as the lack of the cross-linked polymer or specific cross-linked polymer in Exhibit 26.

The secondary references that are cited, are cited, I think, to provide, you know, support for herbal active agents. The dose of -- the formulations in there are either liquids, such as mouthwashes, or they're toothpastes. There is no disclosure of bioadhesive component at all, let alone the concentration we're talking about, and obviously, no disclosure of the polymers that we're talking about, as well. Thank you.

JUDGE SPIEGEL: We've peppered you so much with questions.

MR. TERAPANE: Oh, that's fine.

JUDGE SPIEGEL: All right.

MR. TERAPANE: Not a problem.

JUDGE SPIEGEL: Thank you very much, sir.

MR. TERAPANE: Any other -- anything else we can answer for you, before we --

JUDGE WALSH: I have one, one more question.

MR. TERAPANE: Sure, absolutely, please.

JUDGE WALSH: Is there anything specific in the specification that imposes a limiting definition of the word mucoadhesive?

MR. TERAPANE: I don't believe that there is. I do know that we have some disclosure about how you can measure the adhesive force of a material, but I don't -- let me see. We say the term -- excuse me. We do define it explicitly at claim -- excuse me. I'm in the published applications. I apologize. It's in paragraph 53 and it says "The term bioadhesive, as used herein, means an adhesive which attaches, and preferably strongly attaches, to mucosal tissue upon hydration. Indeed, to qualify as a bioadhesive, a substance must be capable of maintaining adhesion in moist or wet in vivo environments."

And then we also go on to talk about self-adhesive, where it is -- you know, it attaches, once you place it on the site, without having to do anything additional to it.

That's actually an important point, because one of the things about the --

JUDGE WALSH: Is it Nagai where you have to wet it first?

MR. TERAPANE: No, no. The formulation in Nagai is you actually have to wet that composition first, before you then apply it to the site of interest.

DR. DOMB: Inoue.

MR. TERAPANE: I'm sorry. Inoue, excuse me, right.

DR. DOMB: Inoue.

In our case, if you wet it -- if you wet it, then you will not get an adhesion. So it has to be dry, applied onto the surface, and the surface is moisturized, but not liquid, for example. This is the way -- how it penetrates and forms the --

MR. TERAPANE: Any other questions we can answer?

JUDGE MILLS: I don't have any questions.

JUDGE SPIEGEL: Thank you so much, sir.

MR. TERAPANE: Thank you very much for your time. I appreciate it.

Whereupon, the proceedings, at 9:37 a.m., were concluded.